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Date: May 24, 2010 Signature: _____ (Quyen Nguyen)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/612,109
Confirmation No.:	3376
Filing Date:	July 1, 2003
Inventor(s):	Richard C. EWERS et al.
Title:	DELIVERY SYSTEMS AND METHODS FOR GASTRIC REDUCTION
Examiner:	Hand, Melanie Jo
Group Art Unit:	3761

REASONS SUPPORTING PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the non-final Office Action mailed November 23, 2009 ("the Office Action"), in the above-identified United States Patent Application. Filed herewith is a Notice of Appeal and a petition and fee for a three month extension of time. No fee is required for the Notice of Appeal because the fee has already been paid for a Notice of Appeal previously filed on June 2, 2009 in this application. However, the Commissioner is authorized to charge any other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02110**. A pre-appeal brief review is requested for the reasons set forth below.

INTRODUCTION

This application relates generally to a delivery catheter used to manipulate tissue and to deliver tissue anchors into tissue. The catheter is adapted for use in a gastric reduction system to form and maintain tissue folds endoluminally, e.g., via a catheter that is inserted through a patient's mouth and esophagus and into the patient's stomach.

Embodiments of the delivery catheter are shown in FIGS. 12 and 15B, which are reproduced below. The catheter 11 includes an elongated flexible tube having a lumen and a needle 16 disposed for translation through the lumen. A push rod translates within a lumen of the needle to eject an anchor 22 out of the distal end of the delivery catheter. A coil screw 24 having a sharpened distal tip 25 is formed on the distal end of a shaft that is translatable through a separate lumen 135 of the flexible tube.

During operation, the delivery catheter is inserted through a patient's mouth and esophagus E, and into the stomach S. (See, e.g., FIG. 12). The coil screw 24 is engaged to the tissue wall W and the needle 16 is advanced into the tissue wall W. A push rod then ejects the anchor(s) 22 out of the distal end of the delivery catheter and through the tissue wall W. The anchor(s) 22 are attached to one or more sutures 43 that are used to maintain the tissue in a reconfigured state.

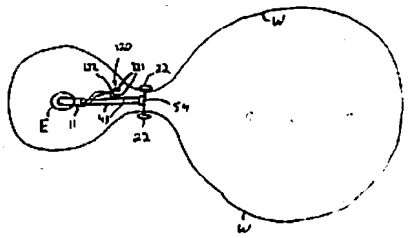


FIG. 12

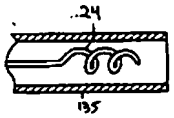


FIG. 15B

ISSUES ON APPEAL

At issue are the following: (a) whether claims 1, 8-10, 46, 49-51, 53, 55, 59, and 60 should be rejected under 35 U.S.C. § 102(b) as being anticipated by USP 5,971,993 to Hussein et al. ("Hussein"), and (b) whether the following claims should be rejected under 35 U.S.C. § 103 for obviousness over the following combinations of references: (i) claims 2, 3, 5, 47, 48, and 56 over Hussein in view of U.S. Patent Pub. No. 2002/058905 to Madrid et al. ("Madrid"); (ii) claims 12, 52, and 58 over Hussein in view of USP 6,656,182 to Hayhurst ("Hayhurst"); and (iii) claim 54 over Hussein in view of U.S. Patent Pub. No. 2002/0087098 to Iwami et al. ("Iwami").

ARGUMENT

I. Rejections Over Hussein Under 35 U.S.C. § 102(b)

All of the independent claims – claims 1, 46, 55, 59, and 60 – were rejected as being anticipated by Hussein. As demonstrated below, these rejections are in error because the Hussein patent does not teach or disclose all of the elements of these claims.

Claims 1 and 60

Figures 4, 12, and 13A of the Hussein patent are shown below. The Office Action identifies: (a) the tubing 79 of the Hussein sheath assembly 71 as corresponding with the "flexible tube" recited in claims 1 and 60, (b) the needle assembly 70 having the needle tip 73 as corresponding with the "needle" recited in the claims, (c) the anchor portion 18 of the myocardial implant or the myocardial implant itself as corresponding with the "at

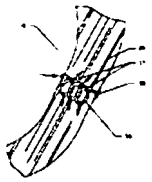
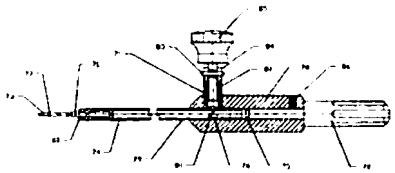


FIGURE 4



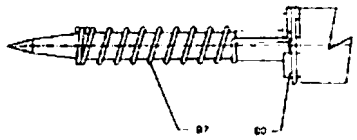


FIGURE 13A

least one anchor" recited in claims 1 and 60, and (d) the coil body 16 and/or 21 of the implant supported by the pin 77 mounted proximal of the needle tip 73 as corresponding with the "coil on a front end of a shaft" recited in both of claims 1 and 60. Contrary to the conclusions stated in the Office Action, the Hussein patent fails to teach or disclose at least the following limitations recited in claims 1 and 60:

- (Claim 1) At least one anchor ***translatably disposed within the needle*** and ***moveable out of the penetrating tip of the needle*** , or
- (Claim 60) At least one anchor ***positioned within the needle*** and ***moveable out of the needle tip during a surgical procedure***;
- (Both Claims) A coil ***on a front end of a shaft that is translatably disposed within a lumen in said tube***; and
- (Both Claims) A ***flexible*** tube.

Turning first to the "anchor" limitations, Hussein's myocardial implant 87 is mounted on the outer surface of the needle tip 73 of the obturator assembly 67 prior to deployment. (See Fig. 13A, col. 6, ll. 10-17). The obturator and implant are then inserted through the heart wall, where the obturator is removed, leaving the implant embedded in the heart wall. (See Figs. 8E-I, col. 4, ll. 31-47). The anchor 18 and/or the full implant therefore are not positioned or translatably disposed ***"within the needle"***, nor are they ***"moveable out of"*** the needle, as recited in claims 1 and 60.

Turning next to the "coil" limitations, the support pin 77 mounted on the needle tip 73 is not a ***" a shaft that is translatably disposed within a lumen"*** of the tubing 79. The support

pin 77 of the Hussein device is not a shaft at all, and it is not described as being translatable in relation to the tubing 79. Moreover, the needle tip 73 and/or needle shaft 74 are already identified in the Office Action as corresponding with the recited "needle translatably disposed within the tube," and therefore cannot be relied upon for the separate recitation of a "translatably disposed" shaft on which the coil is located.

Finally, as for the "tube" limitations, the Hussein patent does not describe the tubing 79 as being "flexible," nor does the Office Action identify any part of the patent for this teaching. On the contrary, the Hussein sheath assembly 71 is delivered through a thoracoscope 66 (see FIG. 11) and is used to support a needle obturator 67 as it penetrates the heart wall 69. Accordingly, there is no reason for the tubing 79 to be flexible.

For all of the foregoing reasons, there can be no anticipation of claims 1 or 60 – or of the claims dependent therefrom – by the Hussein patent.

Claims 46 and 55

Claims 46 and 55 contain "flexible tube" and "coil on a front end of a shaft" limitations that are essentially the same as those discussed above in relation to claims 1 and 60. The errors concerning these limitations are the same as those discussed above, and will not be repeated here. In addition, the Hussein patent fails to teach or disclose at least the following limitations recited in claims 46 and 55:

- (Claim 46) At least one anchor ***positioned within the flexible tube***, and ***moveable out of the flexible tube during a surgical procedure***; or
- (Claim 55) One or more anchors ***stored within the tube*** and ***moveable out of the tube for placement during a surgical procedure***.

As for these "anchor" limitations, the myocardial implants described in the Hussein patent are not ***"positioned within"*** or ***"stored within"*** the tubing 79 of the Hussein device, nor are they ***"movable out of"*** the tubing 79 ***"during a surgical procedure."*** The Office Action does not identify any part of the Hussein patent that provides this teaching. On the contrary, Figure 13A shows the myocardial implant 87 mounted on the ***external*** surface of the sheath assembly. (See col. 6, ll. 10-17).

For all of the foregoing reasons, there can be no anticipation of claims 46 or 55 – or of the claims dependent therefrom – by the Hussein patent.

Claim 59

Claim 59 contains the following limitations that are essentially the same as those discussed above in relation to claims 1 and 60: (i) a "***flexible*** tube," (ii) anchors "***within*** the needle" and "movable ***out*** of the needle," and (iii) a "coil on a front end of a ***shaft***". The errors contained in the Office Action concerning these limitations are essentially the same as those discussed above, and will not be repeated here.

In addition, the Hussein patent fails to teach or disclose "a ***hollow*** needle within the tube" as recited in claim 59. In particular, the Hussein patent does not state whether the needle tip 73 of the described device is "hollow" as recited in claim 59, nor does the Office Action identify any part of the Hussein patent that provides this teaching. On the contrary, the needle tip 73 of the Hussein device serves only as a piercing element. There is therefore no reason for the needle tip 73 to be hollow, or to be modified to be hollow.

For all of these reasons, the Hussein patent does not anticipate claim 59.

II. Rejections Under 35 U.S.C. § 103(a)

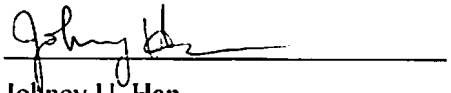
Neither the Madrid publication, the Hayhurst patent, nor the Iwami publication corrects the deficiencies of the Hussein patent discussed in Section I. above. As a result, no combination of these references discloses all of the limitations recited in the pending claims. For this reason, there can be no prima facie case of obviousness of the pending claims based upon the combinations of these references set forth in the Office Action.

For these reasons, the rejections of claims 2, 3, 5, 12, 47, 48, 52, 54, 56, and 58 cannot be supported, and must be withdrawn.

CONCLUSION

In view of the foregoing, the Application is in condition for allowance. The rejections of the pending claims set forth in the Office Action should be withdrawn and the claims passed to issue.

Respectfully submitted,



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